IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION
IN RE: ETHICON, INC.
PELVIC REPAIR SYSTEM,
PRODUCTS LIABILITY LITIGATION MDL NO. 2327

THIS DOCUMENT RELATES TO ALL CASES

NOTICE TO TAKE ORAL DEPOSITION
OF DEFENDANT THROUGH DESIGNATED WITNESSES

TO: Defendant ETHICON, INC. and its Attorneys of Record.

Please take notice that pursuant Rule 30(b)(6) of the Federal Rules of Civil Procedure, Plaintiffs, by and through their counsel, will take the videotaped deposition of Defendant Ethicon, Inc. The witness(es) shall be prepared to testify concerning the subject matter identified in Exhibit "A", attached hereto. The deposition will be taken on Monday, March 18, 2013, beginning at 9:00 a.m. before a person authorized by law to administer oaths, pursuant to Rule 28 of the Federal Rules of Civil Procedure. The deposition will take place at the offices of Riker, Danzig, Scherer, Hyland & Perretti LLP, One Speedwell Avenue, Headquarters Plaza, Morristown, New Jersey, and will continue day-to-day until the examination is completed.

DEFINITIONS

All definitions and rules of instructions set forth in Fed. Rule Civ. P. 30(b)(6) shall apply to all requests for information herein. To the extent a term commonly in use in the medical device industry is not defined herein, it shall be understood to be consistent with the meaning commonly ascribed to that term in the medical device industry.

1. "Concerning" means referring to, describing, evidencing, or constituting. See LR Civ. P 26.2(c)(7).

2. "Defendant", "Ethicon, Inc.", "you" or "your" refers to, without limitation, Ethicon, Inc. and all foreign business entities with which it is or has been affiliated, together

with any predecessor, successor, parent, or subsidiary entity as well as any officer, director, employee, attorney, agent, or representative of any such other business entity previously described herein.

3. "Foreign" shall mean outside the continental United States.

4. "Document" is synonymous in meaning and equal in scope to the usage of this term in Rule 34(a) of the Federal Rules of Civil Procedure and expressly includes writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations stored in any medium from which information can be obtained either directly or, if necessary, after translation by you into a reasonably usable form. A draft or non-identical copy is a separate document. *See* LR Civ. P. 26.2(c)(2); *see also* FR Civ. P 34(a).

5. "Mesh Product" means any product that you developed, designed, distributed, licensed, manufactured, marketed or sold for the treatment of Pelvic Organ Prolapse (POP), Stress Urinary Incontinence (SUI), or hernia repair.

6. "Relevant Time Period" means the time period from when you first developed, designed, distributed, licensed, manufactured, marketed or sold mesh products to the present.

PLAINTIFFS' CO-LEAD COUNSEL

By: ____/s/Thomas P. Cartmell_____

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SCHEDULE A

DEPOSITION SUBJECT MATTER

Pursuant to Rule 30(b)(6), the deponent(s) must have knowledge and shall be able to testify concerning the following subject matters as they relate to documents and things located outside the continental United States concerning Ethicon's mesh products as defined above during the relevant time period:

I. Hardcopy Materials

1. The identity and function of every information technology or management information systems department, division, or equivalent functional groups within your company or provided to you through any outsource service provider, and the identity of the person(s) within it responsible for the retention of any information, data or hard copy documents as well as all information regarding any and all retention policies related to your mesh products.

2. The identity of anyone previously deposed regarding the location, status, indexing, storage and/or organization of hard copy materials located outside the continental United States (and the dates, location and number of depositions taken).

3. The identity, description, contents, implementation and general functions of all systems and associated protocols which exist or have ever existed to identify, store, catalog, assess, and review all documents and data located outside the continental United States under standard retention protocols.

4. All documents providing instructive guidance regarding the location, status, indexing, storage and/or organization of hard copy materials located outside the continental United States.

5. The person or persons responsible for the location, status, indexing, storage and/or organization of hard copy materials located outside the continental United States.

6. All indexes, inventory logs and data of any kind providing guidance regarding the location, status, indexing, storage and/or organization of hard copy materials located outside the continental United States.

7. All policies regarding the criteria for selection of and the process associated with the location, status, indexing, storage and/or organization of hard copy materials located outside the continental United States.

8. Information relating to which portion of the hard copy materials (which are located outside the continental United States) have been scanned or are otherwise electronically available.

9. Information relating to which portion of the hard copy materials located outside the continental United States that have been scanned or are otherwise electronically available have also been OCR'd or are otherwise searchable.

10. Information relating to which portion of the hard copy materials are duplicative of materials captured electronically elsewhere and/or able to specifically identify those materials produced electronically from any index or record of the hard copy materials.

11. Information relating to which portion of the hard copy materials are brochures, marketing materials, external hard drives, flash drives or other portable media.

12. Information and identification of all third party vendors involved in the location, status, indexing, storage and/or organization of hard copy materials located outside the continental United States.

13. Information and identification of the portions of the hard copy materials (located outside the continental United States) language of origin (English, French, German, other).

14. All of your policies and practices (written or oral) concerning litigation or document holds of any kind, as well as the specific litigation or document hold ("hold") issued in response to the instant litigation for all documents holds related to hardcopy and electronically stored information located outside the continental United States, including but not limited to:

a. All details regarding the dissemination of the hold to anyone, including but not limited to employees, agents, or independent consultants or contractors;
b. The date the hold was issued;
c. To whom the hold was sent and in what format;
d. By whom the hold was issued;
e. Any follow-up practices or procedures employed to enforce the hold and make confirm compliance.

15. The identity, description, contents, implementation and general functions of all systems and associated protocols which exist or have ever existed relating to "cleaning out" or discarding materials within the hard copy storage of materials located outside the continental United States.

16. Information relating to the existence of a company-wide retention schedule for hard copy storage materials and any written policies regarding the storage, retention or destruction of hard copy materials located outside the United States.

17. The identity of any and all participants of any inspections involving any plaintiff counsel of any foreign facility storing hard copy materials (and the dates, location and number of inspections).

18. The identity and location of all hardcopy materials, including but not limited to, documents, communications, emails or other recordings located outside the continental United States at any and all time periods from the date Ethicon, Inc. first started researching and developing its mesh products until the present related to the following:

a. The decision to design, develop and manufacture mesh product;

b. The decision to design, develop and standardize a procedure for implantation of mesh products;

c. The implementation of a procedure for the implantation of mesh products, including but not limited to manner in which Ethicon, Inc. would train and qualify physicians to perform mesh procedures;

d. The implementation of a procedure to evaluate and determine physician competency and qualification to perform mesh implantation procedures and/or competency and qualification to continue performing mesh implantation procedures;

e. The decision to include specialized tools with the pelvic mesh device to create a complete pelvic mesh system;

f. The development and coordination of any pre-clinical studies, clinical trials and testing regarding your mesh products;

g. The decision as to whether or not to design, develop, coordinate, create, participate in and/or fund any clinical registries regarding your mesh products;

h. The evaluation of data and results of any pre-clinical studies, clinical trials and testing regarding your mesh products;

i. The substantive preparation and approval of package inserts, IFUs, patient brochures and other labeling for your mesh products (both U.S. and foreign), including the specific dates of use for each such items and any changes thereto;

j. The substantive preparation and approval of all sales aids, physician leave-behinds, patient education materials and any direct to consumer advertising, including the specific dates of use for each such items and any limitations on the geographic scope of use;

k. The substantive preparation and approval of patient safety information sheets (both U.S. and foreign) regarding your pelvic mesh products, including the specific dates of use for each such items and any changes thereto;

l. The substantive preparation and approval of Dear Doctor letters regarding your mesh products and concerning adverse events, conditions, injuries, or unintended outcomes, including the specific dates of use for each such item;

m. The substantive preparation and approval of form clinical communications letters or other communications answering doctor or other healthcare provider inquiries (both U.S. and foreign) concerning your mesh products, including the specific dates of use for each such item;

n. The substantive preparation and approval of training material for use in training your sales representatives, or third party sales representatives regarding your mesh products, including the specific dates of use for each such item;

o. The substantive preparation and approval of training material used in training physicians to utilize your mesh products, including the specific dates of use for each such item;

p. The substantive preparation and approval of training material used in training physicians to remove and/or otherwise deal with complications and adverse events;

q. The oversight and monitoring of Ethicon Inc.'s thought leaders, key opinion leaders, or other consultants (including doctors and other healthcare providers who receive some form of payment or remuneration from Ethicon, Inc. or Johnson & Johnson for work related to your mesh products;

r. The monitoring, investigation and evaluation of post-marketing adverse event reports for your mesh products;

s. The monitoring, evaluation and utilization of unpublished and/or published medical literature regarding your mesh products;

t. The investigation, evaluation and determination as to whether there is an association between your mesh products and any adverse event experienced by patients who were provided your mesh products;

u. The investigation, evaluation and determination as to whether there is a causal connection between your mesh products and any adverse event or injuries;

v. The maintenance of Ethicon Inc.'s finances, budgets and expenditures related to its pelvic mesh products from the date first started developing its pelvic mesh products until the present;

w. The interaction and communication internally or with any outside consultants regarding the safety or efficacy of your mesh products, from the date Ethicon, Inc. first started developing mesh products until the present;

x. The Corrective and Preventative Action Plan ("CAPA") relating to Ethicon, Inc.'s failure to properly maintain documents necessary for regulatory or litigation purposes;

y. The corporate auditing of the conduct of the company and its officers and employees in connection with the development, design, manufacture, distribution, marketing and sales of mesh products from the date Ethicon, Inc. first started developing mesh products until the present;

z. The substance, maintenance and/or sponsorship of any and all website materials and websites concerning mesh products, including the dates of any updates or changes to such items, from the date Ethicon, Inc. first started developing mesh products until the present.

aa. 510(k) compliance, submission, preparation, decision making or any other issues related to 510(k) compliance or submission;

bb. Pre-Clinical Trials- design, preparation, conducting, monitory, analysis and submission;

cc. Clinical Trials- design, preparation, conducting, monitoring, analysis and submission;

dd. Porosity testing

ee. Public Relations;

ff. Media-Training;

gg. Press Releases - design, preparation, drafting and distribution;

hh. Marketing Materials - design, preparation, drafting and distribution;

ii. Firms and/or Individuals, who held themselves out to be experts in the area of regulatory matters;

jj. Package Insert, IFU, patient brochure and other labeling design, preparation, drafting, printing, translation and distribution related to all mesh products manufactured by Ethicon for sale outside the continental United States;

kk. Warnings - design, preparation, drafting and distribution;

ll. Dear Doctor Letters - design, preparation, drafting and distribution;

mm. Doctors, Ph.D.s, consultants and other experts in the area of the use of mesh devices or your mesh products;

nn. Doctors, Ph.D.s, consultants and other experts in the area of urogynecology or injuries to the female anatomy;

oo. Scientific consultants;

pp. Adverse event evaluations, assessments, reporting, databases, or other expertise related to adverse events;

qq. Scientific studies and testing;

rr. Animal Studies conducted;

ss. Drafting of manuscripts and other scientific literature for purposes of publication in any forum, including but not limited to peer-reviewed publications, abstracts, presentations and editorials.

tt. The substance of each package IFU/label and any changes thereto;

uu. The reasons for making each change to the IFU/label; and

vv. The reasons for making each change to the patient brochures;

II. <u>Electronically Stored Material</u>

19. The identity of all employees employed by Ethicon, Inc. during the Relevant Time Period who are or were responsible for managing and maintaining its information technology infrastructure outside the continental United States, including, but not limited to, mail, file, application, database and other servers, cloud, network, local and removable data storage services and/or systems and/or devices, backup systems, desktop computers, laptop computers, tablet devices, personal digital assistants (PDAs), cellular telephones, and other similar electronic systems and devices.

20. The identity of all nonemployee consultants, service providers, contractors, or similar entities retained by Ethicon, Inc. during the Relevant Time Period who are or were responsible for provisioning, installing, servicing, managing, or maintaining its technology infrastructure, including, but not limited to, mail, file, application, database and other servers, cloud, network, local and removable data storage services and/or systems and/or devices, backup systems, desktop computers, laptop computers, tablet devices, personal digital assistants (PDAs), cellular telephones, and other similar electronic systems and devices located outside the continental United States.

21. The identification, description and operational function for all groups of connected computer systems used by Ethicon, Inc., during the Relevant Time Period that enable users to share information and peripherals, collaborate, store information and transfer data, including, but not limited to, local area networks (LANs), wide area networks (WANs), client-server networks, virtual private networks (VPNs), storage area networks (SANs) and network attached storage (NASs); including equipment, devices, components, and network resources that establish and maintain the network environment that are located outside the continental United States.

22. The identification, description and operational function for all third-party remote, cloud or distributed connectivity by and between the computer systems and network environment that are located outside the continental United States used by Ethicon, Inc., during the Relevant Time Period including services known as Software as a Service (SaaS), Platform as a Service (PaaS) and Infrastructure as a Service (IaaS).

23. The identification, description and operational function of any database or data compilation located outside the continental United States used by Ethicon, Inc., during the Relevant Time Period and pertaining to potential health hazards, illnesses, diseases, injuries or side effects of Mesh Product. A Data Dictionary shall be available to reference in order to ascertain the existence of certain types of discrete data elements within any database or data compilation. The Data Dictionary should provide at least the following metadata:

Application	Database	Table	Column Name	Data Type	Example list of valid values

24. The identification, description and operational function of any database, data collection or data compilation located outside the continental United States used by Ethicon, Inc., during the Relevant Time Period and pertaining to any testing or evaluation of Mesh Product. A Data Dictionary shall be available to reference in order to ascertain the existence of certain types of discrete data elements within any database or data compilation. The Data Dictionary should provide at least the following metadata:

Application	Database	Table	Column Name	Data Type	Example list of valid values

25. The identification, description and operation of any database, data collection or data compilation located outside the continental United States used by Ethicon, Inc., during the Relevant Time Period and pertaining to any marketing or labeling of Mesh Product. A Data Dictionary shall be available to reference in order to ascertain the existence of certain types of discrete data elements within any database or data compilation. The Data Dictionary should provide at least the following metadata:

Application	Database	Table	Column Name	Data Type	Example list of valid values

26. The identification, description and operation of any database, data collection or data compilation located outside the continental United States used by Ethicon, Inc., during the Relevant Time Period and pertaining to any effort to secure domestic or foreign approval for sale

or distribution of Mesh Product. A Data Dictionary shall be available to reference in order to ascertain the existence of certain types of discrete data elements within any database or data compilation. The Data Dictionary should provide at least the following metadata:

Application	Database	Table	Column Name	Data Type	Example list of valid values

27. The identification, description and operation of any collaborative environment, extranet or virtual meeting or conferencing product and/or service located outside the continental United States used by Ethicon, Inc., during the Relevant Time Period in connection with the development, evaluation, approval, labeling, marketing, regulation or safety of Mesh Product.

28. The identification, description and operation of any document or records management system located outside the continental United States used by Ethicon, Inc., during the Relevant Time Period and containing records, documents or ESI pertaining to Mesh Product.

29. A description of and the operation of each e-mail and messaging system located outside the continental United States used by Ethicon, Inc., during the Relevant Time Period and used by any persons involved in the development, evaluation, approval, labeling, marketing, regulation or safety of Mesh Product.

30. The steps (and any auditing of such steps) taken by Ethicon, Inc., and any of its employees to identify and preserve documents, records, communications and electronically stored information located outside the continental United States in connection with the instant litigation and prior, current or anticipated litigation involving the same or substantially similar allegations.

31. A description of policies and procedures of Ethicon, Inc., governing the use of

removable media located outside the continental United States, such as recordable optical media, floppy disks, removable hard drives, flash drives, etc., during the Relevant Time Period.

32. A description of the policies and procedures of Ethicon, Inc., governing the use of remote, cloud, or distributed computing or data storage services located outside the continental United States during the Relevant Time Period.

33. A description of policies, procedures and practices (including rotation and retention schedules) used for backing up computer systems located outside the continental United States owned or used by Ethicon, Inc., and its employees, including a description of any hardware or software (and logs associated with the use of same) used to perform such backups during the Relevant Time Period.

34. A description of policies, procedures and practices of Ethicon, Inc., for archiving or journaling e-mail messages outside the continental United States, including a description of any hardware or software, and any rules, schedules or settings used to perform such archival or journaling during the Relevant Time Period.

35. A description of the components and configuration(s) employed by Ethicon, Inc., for voice messaging systems located outside the continental United States, including all hardware, software, and third-party service providers used during the Relevant Time Period.

36. A description of all policies, procedures, practices and audits pertaining to data retention and destruction outside the continental United States during the Relevant Time Period and a description of all hardware or software used to facilitate the deletion of data subject to any data-retention and/or data-destruction policies and procedures.

37. A description of any and all servers or other network storage devices, desktop computers, laptop computers, tablet devices, personal digital assistants (PDAs), cellular phones,

removable storage media and other similar electronic data storage devices or media located outside the continental United States that have had their contents reformatted, wiped, or overwritten from since the attachment of the preservation duty in connection with this action.

38. A description of any and all information or data storage media or device located outside the continental United States relevant

to this matter that was erased, wiped, deleted, physically destroyed, corrupted, damaged, lost, or overwritten, and what information was lost pursuant to any data retention and destruction policies.

39. The identification and description of any/all information or data provisioned by any/all third-party remote, cloud or distributed applications, services or servers located outside the continental United States that was erased, wiped, deleted, physically destroyed, corrupted, damaged, lost, overwritten, or decommissioned due to discontinuation or migration from any applications, services, service providers or servers and what information was lost pursuant to any data retention and destruction policies.

40. The tools, systems and internal capabilities (including any limitations of same) of Ethicon, Inc., to perform automated collection, search or preservation of documents, records and electronically stored information located outside the continental United States in the company's care and custody or subject to its control.

41. The identity and location of all electronically stored materials, including but not limited to, documents, communications, emails or other recordings located outside the continental United States at any and all time periods from the date Ethicon, Inc. first started researching and developing its mesh products until the present related to the following:

a. The decision to design, develop and manufacture mesh product;

b. The decision to design, develop and standardize a procedure for implantation of mesh products;

c. The implementation of a procedure for the implantation of mesh products, including but not limited to manner in which Ethicon, Inc. would train and qualify physicians to perform mesh procedures;

d. The implementation of a procedure to evaluate and determine physician competency and qualification to perform mesh implantation procedures and/or competency and qualification to continue performing mesh implantation procedures;

e. The decision to include specialized tools with the pelvic mesh device to create a complete pelvic mesh system;

f. The development and coordination of any pre-clinical studies, clinical trials and testing regarding your mesh products;

g. The decision as to whether or not to design, develop, coordinate, create, participate in and/or fund any clinical registries regarding your mesh products;

h. The evaluation of data and results of any pre-clinical studies, clinical trials and testing regarding your mesh products;

i. The substantive preparation and approval of package inserts, IFUs, patient brochures and other labeling for your mesh products (both U.S. and foreign), including the specific dates of use for each such items and any changes thereto;

j. The substantive preparation and approval of all sales aids, physician leave-behinds, patient education materials and any direct to consumer advertising, including the specific dates of use for each such items and any limitations on the geographic scope of use;

k. The substantive preparation and approval of patient safety information sheets (both U.S. and foreign) regarding your pelvic mesh products, including the specific dates of use for each such items and any changes thereto;

l. The substantive preparation and approval of Dear Doctor letters regarding your mesh products and concerning adverse events, conditions, injuries, or unintended outcomes, including the specific dates of use for each such item;

m. The substantive preparation and approval of form clinical communications letters or other communications answering doctor or other healthcare provider inquiries (both U.S. and foreign) concerning your mesh products, including the specific dates of use for each such item;

n. The substantive preparation and approval of training material for use in training your sales representatives, or third party sales representatives regarding your mesh products, including the specific dates of use for each such item;

o. The substantive preparation and approval of training material used in training physicians to utilize your mesh products, including the specific dates of use for each such item;

p. The substantive preparation and approval of training material used in training physicians to remove and/or otherwise deal with complications and adverse events;

q. The oversight and monitoring of Ethicon Inc.'s thought leaders, key opinion leaders, or other consultants (including doctors and other healthcare providers who receive some form of payment or remuneration from Ethicon, Inc. or Johnson & Johnson for work related to your mesh products;

r. The monitoring, investigation and evaluation of post-marketing adverse event reports for your mesh products;

s. The monitoring, evaluation and utilization of unpublished and/or published medical literature regarding your mesh products;

t. The investigation, evaluation and determination as to whether there is an association between your mesh products and any adverse event experienced by patients who were provided your mesh products;

u. The investigation, evaluation and determination as to whether there is a causal connection between your mesh products and any adverse event or injuries;

v. The maintenance of Ethicon Inc.'s finances, budgets and expenditures related to its pelvic mesh products from the date first started developing its pelvic mesh products until the present;

w. The interaction and communication internally or with any outside consultants regarding the safety or efficacy of your mesh products, from the date Ethicon, Inc. first started developing mesh products until the present;

x. The Corrective and Preventative Action Plan ("CAPA") relating to Ethicon, Inc.'s failure to properly maintain documents necessary for regulatory or litigation purposes;

y. The corporate auditing of the conduct of the company and its officers and employees in connection with the development, design, manufacture, distribution, marketing and sales of mesh products from the date Ethicon, Inc. first started developing mesh products until the present;

z. The substance, maintenance and/or sponsorship of any and all website materials and websites concerning mesh products, including the dates of any updates or changes to such items, from the date Ethicon, Inc. first started developing mesh products until the present.

aa. 510(k) compliance, submission, preparation, decision making or any other issues related to 510(k) compliance or submission;

bb. Pre-Clinical Trials- design, preparation, conducting, monitory, analysis and submission;

cc. Clinical Trials- design, preparation, conducting, monitoring, analysis and submission;

dd. Porosity testing

ee. Public Relations;

ff. Media-Training;

gg. Press Releases - design, preparation, drafting and distribution;

hh. Marketing Materials - design, preparation, drafting and distribution;

ii. Firms and/or Individuals, who held themselves out to be experts in the area of regulatory matters;

jj. Package Insert, IFU, patient brochure and other labeling design, preparation, drafting, printing, translation and distribution related to all mesh products manufactured by Ethicon for sale outside the continental United States;

kk. Warnings - design, preparation, drafting and distribution;

ll. Dear Doctor Letters - design, preparation, drafting and distribution;

mm. Doctors, Ph.D.s, consultants and other experts in the area of the use of mesh devices or your mesh products;

nn. Doctors, Ph.D.s, consultants and other experts in the area of urogynecology or injuries to the female anatomy;

oo. Scientific consultants;

pp. Adverse event evaluations, assessments, reporting, databases, or other expertise related to adverse events;

qq. Scientific studies and testing;

rr. Animal Studies conducted;

ss. Drafting of manuscripts and other scientific literature for purposes of publication in any forum, including but not limited to peer-reviewed publications, abstracts, presentations and editorials.

tt. The substance of each package IFU/label and any changes thereto;

uu. The reasons for making each change to the IFU/label; and

vv. The reasons for making each change to the patient brochures.